UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

November 7, 2006

DP BARCODE: D331418, D331604, D332049, D332051

MRID : 46896401, 46889801, 46889803, 46889804, 46910202

SUBJECT: CDG Solution 3000

REG. NO. OR FILE SYMBOL: 75757-E

DOCUMENT TYPE: **Product Chemistry Review**

Manufacturing-use [ ] OR **End-use Product [X]**

INGREDIENTS (PC Codes): 020503

CAS Number: 10049-04-4

TEST LAB:

SUBMITTER: CDG Research, Inc.

GUIDELINE:

COMMODITIES:

REVIEWER: Chris Jiang **ORGANIZATION: AD**

APPROVER: Karen P. Hicks **APPROVED DATE:** 11/7/06

COMMENT:

TO: **Emily Mitchell\Wanda Henson**
PM Team 32

FROM: Chris Jiang, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510P)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

APPLICANT: CDG Research, Inc.
Action code : A54
Due out date : 12/05/06

Product Formulation

Active Ingredient(s):	**% by wt.**
Chlorine Dioxide	**0.3 %**

BACKGROUND:

The registrant has submitted a product chemistry package in support of this end-use product for water disinfection. The package includes a label, a Confidential Statement of Formula, and studies that have been identified as MRIDs 46896401, 46889801, 46889803, 46889804, and 46910202. The contractor did a primary review of this submission and Product Science Branch has done a secondary review which supersedes the primary review.

FINDINGS:

1. The concentration of the active ingredient on the Confidential Statement of Formula (CSF dated July 12, 2006) is inconsistent with the label declaration. The registrant did not adjust for the purity of the source of the active ingredient. In addition, the CSF appears to be a pre-reaction CSF because the production process mentions ingredients that seem to be impurities as they are not listed on the CSF.

2. The certified limits are **unacceptable** as the label and the CSF disagree with respect to the nominal concentration.

3. The enforcement analytical method is **unacceptable**. The submitted method must list the materials and chemicals that are used in the titration, describe the procedure of how to prepare the solutions used in the method, define the equation to be used with all variables denoted, and delineate the range where this method is suitable. The registrant must also indicate the catalog number where the pH 7 buffer was purchased as not all pH 7 buffers are equal.

4. The physical state is **unacceptable** as it was not addressed in the submission.

5. The relative density is **unacceptable** as it was not addressed in the submission. This test must be done under GLP compliance.

6. The pH is **unacceptable** as the pH was not addressed in the submission. This test must be done under GLP compliance. This requirement was only addressed on the CSF as 7.

7. The oxidation/reduction potential is **unacceptable** as it was not addressed in the submission. This test must be done under GLP compliance.

8. The flammability is **unacceptable** as it was not addressed in the submission. The test must be done under GLP compliance.

9. The explodability is **unacceptable** as it was not addressed in the submission. The test must be done under GLP compliance.

10. The study for storage stability is **unacceptable** as the study was not done under GLP compliance.

11. The viscosity is **unacceptable** as it was not addressed in the submission. The test must be done under GLP compliance.

12. The miscibility is **unacceptable** as it was not addressed in the submission. The test must be done under GLP compliance.

13. The corrosion characteristics are **unacceptable** as they were not addressed in the submission. The test must be done under GLP compliance. In the submission, the registrant states that the test material is corrosive, but there is no data that substantiates this claim.

14. The dielectric breakdown voltage is **unacceptable** as it is not addressed in the submission. The test must be done under GLP compliance.

15. The registrant wishes to waive all the acute toxicity requirements and states that the company will take the worst-case scenario which is classification of all categories with a toxicity category of II. (This is the company's interpretation). However, the worst-case scenario is actually a categorization of all categories into a toxicity category of I. This toxicity profile would entail labeling with skull and crossbones and language which would be overlabeling of the product. Therefore, no labeling can be determined at the present time for this product.

CONCLUSIONS:

1. Product Science Branch of Antimicrobials Division finds the submission for 075757-E to be unacceptable. The registrant must correct the deficiencies discussed in the findings for successful registration to proceed. It is recommended that the tests for acute toxicity be conducted under GLP compliance.